

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicants: Lara Madison, Gjalt W. Huisman, and Oliver P. Peoples

Serial No.: 09/235,875

Group Art Unit: 1638

Filed: January 22, 1999

Examiner: A. Nelson

For: TRANSGENIC SYSTEMS FOR THE MANUFACTURE OF  
POLY(3-HYDROXY-BUTYRATE-CO-3-HYDROXYHEXANOATE)

Assistant Commissioner for Patents  
Washington, D.C. 20231

**RESPONSE TO RESTRICTION REQUIREMENT**

Sir:

Responsive to the Office Action mailed July 25, 2000, please consider the following remarks.

**The Restriction Requirement and Election**

The Office Action divided claims 1-34 into twelve groups: Group I, claims 1-8, 11-27, and 31-33, drawn to a transformation method with PHB polymerase DNA; Group II, claims 1-8, 11-27, and 31-33, drawn to a transformation method with PHA polymerase DNA; Group III, claims 1-8, 11-27, and 31-33, drawn to a transformation method with  $\beta$ -ketothiolase DNA; Group IV, claims 1-8, 11-27, and 31-33, drawn to a transformation method with  $\beta$ -ketoacyl-CoA reductase DNA; Group V, claims 1-8, 11-27, and 31-33, drawn to a transformation method with D-specific enoyl-CoA hydratase DNA; Group VI, claims 1-8, 11-27, and 31-33, drawn to a

transformation method with butyryl-CoA dehydrogenase DNA; Group VII, claims 1-8, 11-27, and 31-33, drawn to a transformation method with butyryl-CoA dehydrogenase DNA; Group VIII, claims 1-8, 11-27, and 31-33, drawn to a transformation method with 3-hydroxybutyryl-CoA dehydrogenase DNA; Group IX, claim 28, drawn to a method of producing polyhydroxybutyrate-co-3-hydroxyhexanoate; Group X, claim 29, drawn to a method for producing 3-hydroxyhexanoate copolymers with butyrate; Group XI, claim 30, drawn to a method for producing 3-hydroxyhexanoate copolymers with butanol; and Group XII, claim 34, drawn to polyhydroxybutyrate-co-3-polyhydroxyhexanoate. Applicants elect, with traverse, to prosecute, Group V claims 1-8, 11-27, and 31-33, drawn to a transformation method with D-specific enoyl-CoA hydratase DNA.

**The Office Action Appears to Contain Errors.**

Groups VI and VII as defined in the Office Action are **identical**. Applicants assume, based on the remainder of the Office Action, that this is a typographical error and that the Examiner meant Group VII is "drawn to a transformation method with crotonase." If this is not the case, then applicants request clarification of what distinction is intended between the two Groups.

According to the Office Action, claims 9 and 10 are not included in *any* of Groups I-XII. Applicants can only presume that the Examiner intended to include claims 9 and 10 in Group V, since that Group is directed to transformation with D-specific enoyl-CoA hydratase. Applicants request identification of the Group to which claims 9 and 10 purportedly belong.

**The Restriction Requirement is Clearly Improper.**

The restriction requirement fails to comport with the procedures for restriction practice set forth in the M.P.E.P. and is clearly unreasonable in view of the application and claims as a whole. At least Groups I through VIII properly should be prosecuted in a single application.

Applicants have developed biological systems for the improved production of specific polyhydroxyalkanoates, that is those which contain 3-hydroxyhexanoate. All of claimed methods of Groups I to VIII use strains of transgenic organisms which synthesize 3-hydroxyhexanoate monomer, whether the *transgene* encodes PHB polymerase or another of the species of enzyme recited in the Markush group. These enzymes are known. Applicants are not **claiming** these species of enzymes, rather they are claiming a common use: synthesizing a PHA contain 3-hydroxyhexanoate as they are known.

Moreover, the "inventions" of I-VIII are clearly related, for example, because they are plainly capable of use together and result in the same specific end product: PHAs which contain 3-hydroxyhexanoate. The Examiner appears to have misunderstood or ignored what applicants *actually claim*. Applicants *claim*, in all of Groups I-VIII, a method specifically for making PHAs which contain 3-hydroxyhexanoate. This method requires in all of Groups I-VIII the step of synthesizing the PHA in a specific transgenic organism. That organism is required to have at least one transgene integrated into the chromosome, which transgene encodes an enzyme selected from the eight specific enzymes recited. It is therefore implicit that the organism can have *more than one* of the transgenes, including ones which encode a different enzyme from the first one. For example, the particular organism may require two different transgenes to encode

two different enzymes required for use in a particular biosynthetic pathway or particular substrate. Thus the purportedly different "inventions" plainly can be used together, so long as the transgenic organism provides the recited function of synthesizing PHA which contains 3-hydroxyhexanoate—irrespective of the particular pathway or substrate.

Furthermore, according to the M.P.E.P., applicants claims properly are prosecuted in a single application, perhaps with a species election to facilitate searching. M.P.E.P. § 803.02 states, in pertinent part, that

"[a] Markush-type claim can include independent and distinct inventions. ... In applications containing claims of that nature, the examiner may require **provisional election of a single species** prior to examination on the merits. The provisional election will be given effect in the event that the Markush-type claim should be found not allowable."

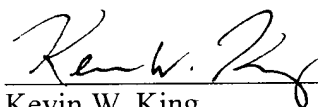
(emphasis added).

Consequently, **a species election rather than a restriction of invention is the appropriate course of action when an application contains a Markush-type generic claim that the Examiner believes to include a plurality of independent and distinct inventions.** Applicants therefore submit that the present restriction requirement is improper, as applicants' claim 1 includes a Markush group of enzymes corresponding to the "species" of transformation method forming the basis of the restriction requirement (i.e. the "species" of Examiner's Groups I through VIII).

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Applicants therefore respectfully request withdrawal of the restriction requirement, or in the alternative, modification of the restriction requirement to group together the claims (and "inventions") of Groups I through VIII, to prosecute claims 1-27 together in the present application.

Respectfully submitted,



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Date: August 24, 2000

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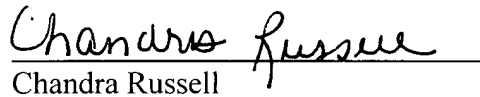
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**Certificate of Mailing under 37 CFR § 1.8(a)**

I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date shown below with sufficient postage as first-class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

  
Chandra Russell

Date: August 24, 2000